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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,152

Applicant(s)

YUKIMASA ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/043,265.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-36 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 21-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of composition and method claims 21-34 are not adequately enabled solely based on squalene synthetase inhibition provided in the specification. Claims 31-34 are to a method for treating any and all diseases and/or conditions associated with squalene synthetase, which is not remotely enabled. The scope of claims 31-34 includes diseases and/or conditions not even known at this time, which may be associated with squalene synthetase. While the treatment of hyperlipidaemia has been linked with squalene synthetase the art does not recognize use of such inhibitors as broad based drugs for treating all disorders instantly embraced. Additionally, instant claim language embraces disorders not only for treatment but also for the prophylaxis, which is not remotely enabled.

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing

out the mere germ of an idea does not constitute enabling disclosure. Genentech Inc. v. Novo Nordisk 42 USPQ2d 1001.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 2, 3 and 12-15 recite the limitation "1 to 3 substituents" in the definitions of R. There is insufficient antecedent basis for this limitation in the claims. There is no indication in claim 1 that R can have more than one substituent "optionally substituted by [a] hydroxyl group".
- b) Claim 4 recites the limitation "3-hydroxy-2-hydroxymethyl-2-methylpropyl, 3-acetoxy-2-hydroxymethyl-2-methylpropyl and 3-acetoxy-2-acetoxymethyl-2-methylpropyl" in the definition of R. There is insufficient antecedent basis for this limitation in the claims. There is no indication in claim 1 that R can have more than one substituent "optionally substituted by [a] hydroxyl group".
- c) Claim 8 is vague and indefinite in that it is not known what is meant by 1,2,3,4-tetrahydroisoquinolinyl in the definition of the substituents of the (a), (b) and (c) groups in the definition of the hydrocarbon group of R₃. See the paragraph labeled (x) on page 96.
- d) Claim 8 is vague and indefinite in that it is not known what is meant by pydinyI in the definition of the substituents of the (a), (b) and (c) groups in the

definition of the hydrocarbon group of R_3 . See the paragraph labeled (xi) on page 96.

e) Claim 8 is vague and indefinite in that it is not known what is meant by the second occurrence of a comma after the definition of the substituents of the (a), (b) and (c) groups in the definition of the hydrocarbon group of R_3 . See the comma, which appears after the paragraph labeled (xi) on page 96.

f) Claim 8 is vague and indefinite in that the groups (d) and (e) may be substituted with seven possible moieties, however, the moiety following the (vi) moiety is (v) halogen. It is believed that the applicants intend (vii) halogen. Clarification is required. See line 5 on page 97.

g) Claims 8 and 10 are vague and indefinite in that it is not known what is meant by 2,3-dihydro-3-oxo-1,2,4-**tetrazolyl** and 2,3-dihydro-3-thioxo-1,2,4-**tetrazolyl** in the definition of the heterocyclic group of R_3 . See the paragraph labeled (2) on page 97.

h) Claims 8 and 20 are vague and indefinite in that it is not known what is meant by 2,5-dihydro-5-oxo-1,2,4-oxazolyl. Oxazolyl is a heterocyclic ring which contains a oxygen atom and a nitrogen atom in the 1,3 configuration of the ring. Clarification is required.

i) Claim 9 recites the limitation " C_{2-7} alkanoyl- C_{1-6} alkyl" in the definition of the substituents on the cyclic amino of R_2 and R_3 together with the adjacent nitrogen atom. There is insufficient antecedent basis for this limitation in the claims.

- j) Claim 10 is vague and indefinite in that it is not known what is meant by hydrog n in the second line of page 100.
- k) Claims 13 is vague and indefinite in that it is not known what is meant by repres nted and th formula in the last line of page 100.
- l) Claim 16 recites the limitation "3-hydroxy-2-hydroxymethyl-2-methylpropyl (in the second and third species on page 101)" in the definition of R. There is insufficient antecedent basis for this limitation in the claims.
- m) Claim 16 is vague and indefinite in that it is not known what is meant by acetamid , in the third line from the bottom of page 101.
- n) Claim 16 is vague and indefinite in that it is not known what is meant by 2-m thylpropyl in the last line on page 101.
- o) Claim 17 recites the limitation "3-acetoxy-2-acetoxymethyl-2-methylpropyl (in the second, fourth and sixth species on page 102)" in the definition of R. There is insufficient antecedent basis for this limitation in the claims.
- p) Claim 18 recites the limitation "3-hydroxy-2-hydroxymethyl-2-methylpropyl (in the second species on page 102) and 3-acetoxy-2-acetoxymethyl-2-methylpropyl (in the last species of claim 18 on page 103)" in the definition of R. There is insufficient antecedent basis for this limitation in the claims.
- q) Claim 18 recites the limitation "benzoxazepine-3-one" in the nomenclature of all four species. There is insufficient antecedent basis for this limitation in the claim.

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- r) Claim 18 is vague and indefinite in that it is not known what is meant by [1H(or 3H)-t trazol-5-yl]methyl in the last line of page 102.
- s) Claim 18 is vague and indefinite in that it is not known what is meant by the nomenclature of the first species, which appears on page 103, which is missing a close parenthesis.
- t) Claim 20 recites the limitation "one or two hydroxyl groups" in the definition of R. There is insufficient antecedent basis for this limitation in the claims.
- u) Claim 20 is vague and indefinite in that it is not known what is meant by C₃₋₇ cycloalkyl.
- v) Claim 20 is vague and indefinite in that it is not known what is meant by the second occurrence of a comma after the definition of the substituents of the (a), (b) and (c) groups in the definition of the hydrocarbon group of R₃. See the comma, which appears after the paragraph labeled (xi) on page 104.
- w) Claim 20 contains a typographical error in that there is a period in the middle of the claim. See the seventh line from the bottom of page 104.
- x) Claims 22-25 are substantial duplicates of claim 21 as the only difference is a statement of the intended use, which is not given material weight. Note *In re Tuominen* 213 USPQ 89.
- y) Claims 26-30 provides for the use of the compounds of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is

indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

z) Claims 31-34 are vague and indefinite in that the claim provides for the use of claimed compounds, but the claim does not set forth any steps involved in determining which are the diseases capable of being ameliorated by inhibiting squalene synthetase. Determining whether a given disease responds or does not respond to such an inhibitor will involve undue experimentation. Suppose that a given drug, which has inhibitor properties in vitro, when administered to a patient with a certain disease, does not produce a favorable response. One cannot conclude that specific disease does not fall within this claim. Keep in mind that:

A. It may be that the next patient will respond. No pharmaceutical has 100% efficacy. What success rate is required to conclude our drug is a treatment? Thus, how many patients need to be treated? If "successful treatment" is what is intended, what criterion is to be used? If one person in 10 responds to a given drug, does that mean that the disease is treatable? One in 100? 1,000? 10,000? Will the standard vary depending on the current therapy for the disease?

B. It may be that the wrong dosage or dosage regimen was employed. Drugs with similar chemical structures can have markedly different pharmacokinetics and metabolic fates. It is quite common for pharmaceuticals to work and or be safe at one dosage, but not at another that is significantly higher

or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in divided dosages? The optimum route of administration cannot be predicted in advance. Should our drug be given as a bolus iv or in a time release po formulation. Thus, how many dosages and dosage regimens must be tried before one is certain that our drug is not a treatment for this specific disease?

C. It may be that our specific drug, while active in vitro, simply is not potent enough or produces such low concentrations in the blood that it is not an effective treatment of the specific disease. Perhaps a structurally related drug is potent enough or produces high enough blood concentrations to treat the disease in question, so that the first drug really does fall within the claim. Thus, how many different structurally related inhibitors must be tried before one concludes that a specific compound does not fall within the claim?

D. Conversely, if the disease responds to our second drug but not to the first, both of which are inhibitors in vitro, can one really conclude that the disease falls within the claim? It may be that the first compound result is giving the accurate answer, and that the success of second compound arises from some other unknown property, which the second drug is capable. It is common for a drug, particularly in the treatment of pain, schizophrenia, depression etc., to work by many mechanisms. The history of psychopharmacology is filled with drugs, which were claimed to be a pure receptor XYX agonist or antagonist, but upon further experimentation shown to affect a variety of biological targets. In fact, the

development of a drug for a specific disease and the determination of its biological site of action usually precede linking that site of action with the disease. Thus, when mixed results are obtained, how many more drugs need be tested?

E. Suppose that our drug is an effective treatment of the disease of interest, but only when combined with some totally different drug. There are for example, agents in antiviral and anticancer chemotherapy, which are not themselves effective, but are effective treatments when the agents are combined with something else.

Consequently, determining the true scope of the claim will involve extensive and potentially inconclusive research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

aa) Claim 35 is vague and indefinite in that it is not known what is meant by d fined in the second from the last line on page 107.

ab) Claim 36 is vague and indefinite in that it is not known what is meant by claim d in the first line on page 108.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 26-30 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

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definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 5-8 and 21-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Yukimasa et al., WO 95/21834. Yukimasa teaches the compounds, compositions and method of use of the instant invention where R₁ is methyl, W is chlorine, R is neopentyl and X is alanine or t-butyl ester of alanine. See compounds (2) and (4) on page 19.

5. Claims 1, 5-8 and 21-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Yukimasa et al., U.S. 5,726,306. Yukimasa teaches the compounds, compositions and method of use of the instant invention where R₁ is methyl, W is

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chlorine, R is neopentyl and X is alanine or t-butyl ester of alanine. See compounds (2) and (4) in example 170.

6. Claims 1-8 and 20-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Hamanaka et al., U.S. 6,537,987. Hamanaka teaches the compounds, compositions and method of use of the instant invention where R₁ is methyl, W is chlorine, R is neopentyl and X is substituted piperidin-1-ylcarbonyl or pyrrolidin-1-ylcarbonyl. See compounds such as those found in claims 4, 7, 10, 12, 17, 25, 46b, 46d, 48, 49, etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yukimasa et al., EP 0 567 026 (U.S. equivalent U.S. 5,885,979 and U.S. 5,726,306).

The generic structure of EP '026 encompasses the instantly claimed compounds (see Formula I, page 2, more specifically Formula Id, page 14), for the same use (squalene synthetase inhibitors) and by the same process (see page 15) as claimed herein.

Examples such as compound numbers 13, 14, 15, 18, 19, 20, 23 and 25-29 in Tables 31-33 and compound numbers 1-6 in Tables 37-40, 56, 57, 58 and 59 differ only in the nature of the R₁, R₂, R₃, X and Y substituents of formula I and the R₁, R₂, R₃, R₆, R₇, m, n and Y substituents of formula Id. Pages 2-3 defines the substituent "R₁ as hydrogen

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atom or an optionally substituted hydrocarbon group; R_2 and R_3 independently stand for hydrogen atom, an optionally substituted lower alkyl group, an optionally substituted phenyl group or an optionally substituted aromatic heterocyclic group; X stands for a bond or a spacer having the chain length of 1 to 7 atoms; Y stands for an optionally esterified or thioesterified carboxyl group, an optionally substituted hydroxyl group, an optionally substituted amino group, an optionally substituted phenyl group, an optionally substituted carbamoyl group or a N-containing heterocyclic residue having hydrogen atom capable of being deprotonated". Additionally, "optionally substituted phenyl group of R_2 and R_3 is "exemplified by halogen atom, optionally substituted C_{1-4} lower alkyl groups, optionally substituted C_{1-4} lower alkoxy groups, optionally substituted hydroxyl groups, nitro group and cyano group, and "optionally substituted phenyl group" may have 1 to 3 of these substituents". Compounds of the instant invention are generically embraced by EP '026 in view of the interchange ability of R_1 , R_2 , R_3 , X and Y substituents of the benzoxazepine ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for 2,3-dimethoxyphenyl for the R_2 or R_3 substituent of the reference as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

8. Claims 1-8 and 20-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamanaka et al., U.S. 6,537,987. The generic structure of U.S. '987 encompasses the instantly claimed compounds (see Formula I), for the same use (squalene synthetase inhibitors) as claimed herein. Examples such as compound in claims 4, 7,

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10, 12, 17, 25, 46b, 46d, 48, 49, etc. differ only in the nature of the R_1 , R_2 , R_3 , R_4 , R_9 , R_{10} , T, Z and Z_1 substituents of formula I. Column 2, line 52 through column 4, line 14 defines the substituent " R_1 and R_2 are each independently hydrogen, halo.....; R_3 , R_9 and R_{10} are each independently C_{1-4} alkoxy....; R_4 is C_1 - C_7 alkyl optionally mono-, di-, or tri- substituted wherein the substituents are independently chosen from hydroxyl, oxo, (C_1 - C_4)alkyl, amino, carboxy, thiol, (C_1 - C_4)alkoxy, fluorinated (C_1 - C_4)alkoxy having from 1 to 9 fluorines, (C_1 - C_4)alkylthio, (C_1 - C_4)alkylsulfinyl, (C_1 - C_4)alkylsulfonyl, mono-N- or di-N,N-(C_1 - C_4)alkylamino, mono-N- or di-N,N-(C_1 - C_4)alkylaminocarbonyl, mono-N- or di-N,N-(C_1 - C_4)alkylaminosulfonyl, etc.; T forms a four to seven membered mono-aza, saturated ring, said ring optionally containing thio or oxo and said ring optionally mono-substituted on carbon with hydroxyl, (C_1 - C_4)alkoxy or carboxyl; Z is carboxyl, (C_1 - C_4)alkoxycarbonyl, mono-N- or di-N,N-(C_1 - C_4)alkylaminocarbonyl, aminocarbonyl, cyano, hydroxyaminocarbonyl, - $C(O)N(H)SO_2R_5$, tetrazol-5-yl, 4,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl, tetrazol-5-yl-aminocarbonyl, 3-oxoisoxazolidin-4-yl-aminocarbonyl, $N(R_{12})CONR_{13}R_{14}$, $N(R_{12})CO_2(C_1-C_4)$ alkyl or $N(R_{12})COR_{15}$; and Z_1 is H, carboxyl, hydroxyl, (C_1 - C_4)alkoxy or (C_1 - C_4)alkoxycarbonyl. Compounds of the instant invention are generically embraced by U.S. ;987 in view of the interchange ability of R_1 , R_2 , R_3 , R_4 , R_9 , R_{10} , T, Z and Z_1 substituents of the benzoxazepine ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for 2,3-dimethoxyphenyl for the R_2 or R_3 substituent of the reference as well as other

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possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 16-18 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 16-18 of prior U.S. Patent No. 6,613,761. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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10. Claims 31-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6, 7, 9-15, 17-19, 22 and 25 of U.S. Patent No. 5,885,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. '979 claims embrace the method of use of the instant invention where Ring A and Ring J' form a benzooxazepine ring and R_2 or R_3 is an optionally substituted phenyl group.

11. Claims 1-9, 11, 14, 15, 17, 18, 20-25, 31, 34 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 8-16 of U.S. Patent No. 5,726,306. Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. '306 claims embrace the compounds, compositions and method of use of the instant invention where R_2 or R_3 is an optionally substituted phenyl group.

12. Claims 1-18, 20-25, 31-34 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,110,909. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound, composition and method of use claims of U.S. '909 are embraced by the compounds, composition and method of use of the instant invention R_1 is methyl; W is chlorine; R is 3-hydroxy-2,2-dimethylpropyl or 3-acetoxy-2,2-dimethylpropyl and X is tetrazolyl, N-methylsulfonylcarbamoyl or N-[2-(pyrrolidin-1-yl)ethyl]carbamoyl.

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13. Claims 1-15 and 19-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 and 19-27 of U.S. Patent No. 6,613,761. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound, composition and method of use claims of U.S. "761 are embraced by the compounds, composition and method of use of the instant invention R_1 is a lower alkyl group; W is a halogen atom; R is a lower alkyl substituted by 1 to 3 hydroxy groups which may be substituted; and X is an optionally substituted carbamoyl group or an optionally substituted heterocyclic group having a deprotonatable hydrogen atom.

14. Claims 1-34 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/480,707. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula (I) of the instant invention is embraced by the compounds, compositions and method of use of the compounds of formula (I) of copending Application No. 10/480,707 where Ring A and Ring J' form a benzoxazepine ring as specifically shown by formulae (Ib) and (Ic).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1-34 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52

of copending Application No. 10/416,239. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula (I) of the instant invention is embraced by the compounds, compositions and method of use of the compounds of formula (I) of copending Application No. 10/416,239 where Ring A and Ring J' form a benzoxazepine ring as specifically shown by formulae (Ib) and (Ic).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

16. Claim 35 is improperly dependent in that it does not refer to the claims from which they depend in the alternative.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "Brenda Coleman". The signature is fluid and cursive, with a long horizontal flourish extending from the end of the name.

Brenda L. Coleman
Primary Examiner Art Unit 1624
September 26, 2005